Brief Report

A Pilot Study of Comparison of BCPAP vs. VCPAP in Preterm Infants with Early Onset Respiratory Distress

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Summary

Background: Bubble continuous positive airway pressure (BCPAP) is a low-cost nasal CPAP delivery system with potential benefits for developing nations. The objective of the study was to compare the efficacy and safety of BCPAP with ventilator CPAP (VCPAP) in preterm neonates with moderate respiratory distress.

Methods: In a pilot randomized controlled trial, 30 preterm neonates (gestation <37 weeks) with Silverman–Anderson score between 5 to 7 and oxygen requirement >30% within first 6 h of life were randomly allocated to BCPAP or VCPAP after informed parental consent. Proportion of neonates with success or failure, while using the allocated mode of CPAP delivery (primary outcome) was compared.

Results: The success rate was comparable [VCPAP: 80% (12/15) vs. BCPAP: 87% (13/15)] between the two groups. Dislodgement was commonest problem with equal frequency [10/15, (67%)] in each group.

Conclusion: BCPAP appears to be a promising method of CPAP delivery in preterm neonates with moderate respiratory distress.

Background

Nasal continuous positive airway pressure (CPAP) is an established modality of respiratory support in preterm neonates [1]. Given its low cost Bubble CPAP (BCPAP) has a potentially significant role in resource-poor nations [2, 3]. However comparative studies to determine the best delivery system for nasal CPAP are lacking. BCPAP has been reported as a safe and effective method for delivering CPAP during peri-extubation phase in ventilated preterm infants [4]. Considering limited availability of data, we aimed to compare the efficacy and safety of BCPAP with ventilator CPAP (VCPAP) in preterm neonates with moderate respiratory distress.

Design and setting

A pilot randomized controlled trial (August 2007 to April 2008) was conducted in a tertiary neonatal intensive care unit at KEM Hospital, Pune, India.

Eligibility criteria

Preterm neonates (gestation <37 weeks) with Silverman–Anderson (SA) score between 5 and 7, and oxygen requirement >30% within first 6 h of life were eligible for enrolment following informed parental consent.

Exclusion criteria

(i) Lack of parental consent, (ii) significant congenital malformations, (iii) postnatal age >6 h and (iv) severe respiratory distress defined by: SA score >7, oxygen requirement >60%, $\text{PCO}_2$ >65 mm Hg and alveolar to arterial oxygen gradient (A-a $\text{DO}_2$) >180 mm Hg on a blood gas done within 30 min before randomization.

Neonates with severe respiratory distress as defined above were excluded from the study. These neonates were ventilated and received early rescue surfactant therapy as per unit policy.

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Randomization

Neonates eligible for enrollment were randomly allocated to either BCPAP or VCPAP group using computer generated random numbers contained in sealed envelopes with labels wrapped in opaque aluminum foil. Given the nature of interventions blinding of primary research team members to the allocation status of neonates was not possible. The statistician and outcome assessors were however blinded. Concealment of allocation was optimized by assuring recording of basic demographic and clinical data of neonates with parental consent before opening of coded envelopes.

Primary outcome

Proportion of neonates with success or failure of the allocated mode of delivery was the primary outcome. Success was defined as an improvement in oxygen requirement (<30%) and SA score (<3) leading to successful stoppage of CPAP and no need of respiratory support for next 7 days. Failure was defined as worsening SA scores, rise in oxygen requirement >60% and CPAP needs >8 cm H2O.

Secondary outcomes

These included complications such as pneumothorax and injury to the nasal septum.

Equipment

Fischer Paykel BCPAP generator with blender and Columbia BCPAP setup (Fischer and Paykel Health Care, Auckland, New Zealand) were used for delivering BCPAP. For VCPAP Argyle binasal prongs were used to connect to Bear Cub 750 PSV ventilator (Bear Medical Systems, Inc. Palm Springs, CA 92262).

Statistical methods

For statistical analysis SPSS version 10 was used. The Student’s t-test and chi-square test were used for numerical and dichotomous variables, respectively. Probability p-values <0.05 were considered significant.

Results

The distribution of neonates with respiratory distress during study period is shown in Fig. 1. The median (IQR) gestational age and birth weight of the enrolled neonates were 33.5 weeks (30.7–35.0) and 1645 g (1275–2055), respectively. The mean duration of CPAP was comparable in neonates with respiratory distress syndrome (RDS): VCPAP 25.5 h and BCPAP 25.9 h. RDS was the most common radiological diagnosis in both groups: VCPAP 67% (10/15) and BCPAP 74% (11/15). The success rate was comparable (80 vs. 87%, p = 0.62) in VCPAP vs. BCPAP groups. The overall success rate was 83% (25/30). Success of CPAP was not related to any of the demographic variables.

Dislodgement of CPAP was the most frequent problem (20/30, 67%) with equal frequency in each group (10/15, 67%). Two neonates, 2/15 (13%), in VCPAP group developed pneumothorax.

Discussion

Currently the role of nasal CPAP in management of respiratory distress is well accepted. Short binasal prongs form the contact device of choice, but the optimal pressure source for the delivery of nasal CPAP still needs to be determined [5]. In a trial of 18...
preterm neonates BCPAP was associated with increased work of breathing compared with variable flow nasal CPAP [6]. Based on these data it was postulated that BCPAP will have greater failure rates. However Lee et al. suggested that ventilation was more effective with BCPAP than VCPAP [4]. In a crossover trial of BCPAP and VCPAP Morley reported no difference in oxygenation and arterial CO₂ [7]. It is important to note that these two trials have involved stable preterm neonates with resolving respiratory disease. The observations that BCPAP improves airway stability at low lung volume [8] and increases surfactant secretion [9] provide rationale for BCPAP in the initial management of respiratory distress.

BCPAP failure is correlated with need for positive pressure at birth, severe RDS and A-a DO₂ >180 mm Hg on arterial blood gas [10]. The higher success rate of BCPAP in our study, 87 vs. 76% by Ammari et al. [10], may relate to the exclusion of

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**Table 5**
Characteristics of neonates with failure vs success of CPAP

<table>
<thead>
<tr>
<th>Characteristic of group</th>
<th>CPAP failure Mean (SD)</th>
<th>Successful CPAP Mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age (weeks)</td>
<td>34.2 (1.3)</td>
<td>32.3 (2.8)</td>
<td>0.12</td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>1977 (437)</td>
<td>1600 (425)</td>
<td>0.06</td>
</tr>
<tr>
<td>Initiation age (h)</td>
<td>3.4 (2.3)</td>
<td>2.4 (1.8)</td>
<td>0.28</td>
</tr>
<tr>
<td>SA score at initiation</td>
<td>6.2 (0.6)</td>
<td>6.1 (0.6)</td>
<td>0.71</td>
</tr>
</tbody>
</table>

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**Table 6**
Morbidity associated with CPAP device

<table>
<thead>
<tr>
<th>Morbidity</th>
<th>VCPAP n (%)</th>
<th>BCPAP n (%)</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilation of nares</td>
<td>5 (33)</td>
<td>7 (47)</td>
<td>12 (40)</td>
</tr>
<tr>
<td>Nasal septal injury</td>
<td>0 (0)</td>
<td>4 (27)</td>
<td>4 (13)</td>
</tr>
<tr>
<td>Skin erosion</td>
<td>2 (13)</td>
<td>7 (47)</td>
<td>9 (30)</td>
</tr>
<tr>
<td>Dislodgement</td>
<td>10 (67)</td>
<td>10 (67)</td>
<td>20 (67)</td>
</tr>
<tr>
<td>Abdominal distension</td>
<td>5 (33)</td>
<td>4 (27)</td>
<td>9 (30)</td>
</tr>
<tr>
<td>Secondary pneumonia</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Air leak</td>
<td>2 (13)</td>
<td>0 (0)</td>
<td>2 (7)</td>
</tr>
</tbody>
</table>

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**Fig. 1.** Distribution of the study neonates.

**Fig. 2.** CPAP success.
neonates with severe respiratory distress. This suggests that early BCPAP is effective for moderate respiratory distress.

Nasal septal injury was seen in 27% (4/15) neonates allocated to BCPAP group; similar incidence of nasal septal injury has been reported by other researchers [12]. The overall incidence of pneumothorax was comparable, 7 (2/30) vs. 10.3%, to that reported by Migliori et al. [13].

The limitations related to the small sample size in this pilot trial need to be considered before interpreting our results. The simplicity and low cost of BCPAP delivery system compared with ventilators makes it an attractive option for neonatal intensive care units in resource-poor setups where management as well as referral to tertiary care centers impose a significant economic burden [14].

Conclusion

The results of our pilot trial indicate that early BCPAP may be a safe and effective modality for managing preterm neonates with moderate respiratory distress. Definitive large trials are needed to confirm this.

References